



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

THE BINDING SITE GROUP, LTD.
C/O MR. PAUL KENNY
HEAD OF REGULATORY AFFAIRS
8 CALTHORPE RD, EDGBASTON
BIRMINGHAM, WEST MIDLANDS, B15 1QT
UNITED KINGDOM

March 18, 2014

Re: k140105

Trade/Device Name: Hevylite™ Human IgA Kappa Kit for use on Siemens BN™ II
Systems and Hevylite™ Human IgA Lambda Kit for use on Siemens
BN™ II Systems

Regulation Number: 21 CFR 866.5510

Regulation Name: Immunoglobulins A, G, M, D, and E Immunological Test System

Regulatory Class: II

Product Code: OPX, OPY

Dated: January 13, 2014

Received: January 15, 2014

Dear Mr. Kenny:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Maria M. Chan -S

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number (if known)

Device Name

Hevylite Human IgA Kappa Kit for use on Siemens BNII and Hevylite Human IgA Lambda Kit for use on Siemens BNII

Indications for Use (Describe)

Hevylite Human IgA Kappa is a quantitative in vitro assay performed on the Siemens BN II nephelometer for the measurement of IgA Kappa (IgA heavy chain and Kappa light chain intact immunoglobulin) in serum. Measurement of Hevylite Human IgA Kappa is used alongside Hevylite Human IgA Lambda to calculate the IgA Kappa / IgA Lambda ratio. The Hevylite Human IgA Kappa / IgA Lambda ratio can be used when monitoring previously diagnosed IgA multiple myeloma and is used in conjunction with other laboratory tests and clinical evaluations. The assignment of complete response is reliant upon other tests including immunofixation, bone marrow and urine assessments.

Hevylite Human IgA Lambda is a quantitative in vitro assay performed on the Siemens BN II nephelometer for the measurement of IgA Lambda (IgA heavy chain and Lambda light chain intact immunoglobulin) in serum. Measurement of Hevylite Human IgA Lambda is used alongside Hevylite Human IgA Kappa to calculate the IgA Kappa / IgA Lambda ratio. The Hevylite Human IgA Kappa / IgA Lambda ratio can be used when monitoring previously diagnosed IgA multiple myeloma and is used in conjunction with other laboratory tests and clinical evaluations. The assignment of complete response is reliant upon other tests including immunofixation, bone marrow and urine assessments.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Maria M. Chan -S